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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/582,817	11/08/2000	Jose Remacle	VANM160.001A	2892

20995 7590 02/10/2005

Knobbe Martens Olson & Bear LLP
2040 Main Street
Fourteenth Floor
Irvine, CA 92614

EXAMINER

SISSON, BRADLEY L

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 02/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/582,817

Applicant(s)

REMACLE, JOSE

Examiner

Bradley L. Sisson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2004 & 05 January 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-34, 40, 41, 44, 45, 47, 49 and 51-64 is/are pending in the application.
- 4a) Of the above claim(s) 32, 33, 49 and 51-63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30, 31, 34, 40, 41, 44, 45, 47 and 64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 June 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Claims 32-33, 49, and 51-63 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 24 May 2002.

Claim Objections

2. Claim 41 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 30, from which claim 41 depends, speaks to the “detection and/or quantification of the signal,” however, claim 30 recites that it is not the signal, but the target molecule that is being “detected and/or quantified.”

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 30-31, 34, 40-4, 44-45, 47, and 64 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably

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convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Attention is directed to the decision in *University of*

Rochester v. G.D. Searle & Co. 68 USPQ2D 1424 (Fed. Cir. 2004) at 1428:

To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. *Vas-Cath*, 935 F.3d at 1563; see also *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 [41 USPQ2d 1961] (Fed. Cir. 1997) (patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that “the inventor invented the claimed invention”); *In re Gosteli*, 872 F.2d 1008, 1012 [10 USPQ2d 1614] (Fed. Cir. 1989) (“the description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed”). Thus, an applicant complies with the written-description requirement “by describing the invention, with all its claimed limitations, not that which makes it obvious,” and by using “such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention.” *Lockwood*, 107 F.3d at 1572.

5. For convenience, claim 30, the only independent claim pending and under consideration, is reproduced below.

30. (Currently amended) A method for the a detection and/or quantification of a target molecule present in a sample, comprising the steps of:

allowing binding between said target molecule and a capture molecule fixed upon a side of the surface of a solid support, said solid support comprising consisting of a compact disc (CD) or digital video disc (DVD) comprising registered data that can be read by a CD reading device, wherein said binding occurs in areas separated from areas comprising registered data, wherein said CD or DVD is not rotating on its axis and does not comprise microchannels;

wherein capture molecules are located on areas of said disc that do not comprise any grooves or registered data, and

wherein the target and capture molecules are nucleic acid molecules or proteins;

treating said CD or DVD in order to obtain a detectable signal resulting from the binding of the target molecule and said capture molecule, wherein said binding results in a precipitate on said CD or DVD, wherein said CD or DVD is not rotating on its axis;

detecting said signal, wherein said signal is not obtained through cleavage of the capture molecule, and

reading the registered data and reading the signal resulting from the binding between said target molecule and said capture molecule, said readings being done when the disc is rotating on its axis in an apparatus comprising two different reading devices.

6. For purposes of examination, claim 30 has been interpreted as not using any means to protect or otherwise shield the registered data from the binding of nucleic acids, or the generation of any precipitate thereon.

7. The claimed method has also been interpreted as encompassing the reading of the registered information prior to, during or after having conducted the binding and detecting parts of the assay, and wherein the surface of the CD and/or DVD has not been treated so as to remove any materials bound to its surface.

8. In accordance with amended claim 30, the capture molecules are to be located "on areas of said disc that do not comprise any grooves or registered data. Such language has been

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interpreted as encompassing there being no means to identify just where on the surface the capture molecules are located, or means by which the reader head can accurately and reproducibly locate, read and record the signal, if any, from which one can then deduct the detection and/or quantification of any target molecule.

9. As presently worded, the solid support may well have mixtures of capture molecules, and/or the binding assay be conducted under conditions whereby non-specific binding occurs. The specification fails to provide the requisite full, clear, and concise written description so as to reasonably suggest that applicant was in possession of the full scope of the claimed invention.

10. In accordance with claim 34, one is to detect the signal by any of “reflection, absorption, and diffraction of a light beam, and variation of a magnetic field.”

11. The specification has been found to provide the following examples:

- Example 1, pages 26-28, “Detection of DNA on CD.” The disc does not comprise registered data, and the binding of DNA to a probe is not achieved by using any “apparatus comprising two different reading devices.” Rather, a picture of the CD was taken.
- Example 2, page 28, “Detection of DNA on CD with maser [laser; *sic*] detection.” Following the application of a silver stain (precipitate), “[t]his CD was recovered with a gold layer to allow a laser CD player to read information written on the CD and to read the interference due to silver precipitate (Fig. 2 and 3).” The specification is silent as to the CD reader comprising “two different reading devices.”
- Example 3, pages 28-30, “Detection of protein on CD by light absorption.” The disc does not comprise registered data, and the formation of immunoglobulin – BSA-

immunoglobulin-peroxidase was not detected with any “apparatus comprising two different reading devices.” Furthermore, the method does not comprise any reading of any registration data. A picture of the CD was taken.

- Example 4, page 30, “Detection of proteins on CD with laser detection.” Similar to Example 3, but the CD was read by a CD reader. Again, no registration data read, and the readings were not performed in an apparatus comprising two different reading devices.
- Example 5, pp. 30-31, “Magnetic detection of DNA or protein on CD.” Prophetic statements of how hybridized DNA or protein on CD can be detected by a magnetic process. No method steps, starting materials, or reaction conditions described.

12. As seen above, none of the examples recite the method steps found in claim 30, the only independent claim under consideration. Clearly, none of the examples teach using a DVD.

13. In Example 2 it is noted that streptavidin-colloidal gold was used to detect biotinylated DNA spotted on the CD. Subsequent to the binding of streptavidin-colloidal gold to the biotinylated probe, “the CD was further incubated 30 min in a solution made of equal volume of Solution A and B from Silver enhancement kit (Sigma, St. Louis, USA) in order to have silver precipitate where positive hybridization occurred. This CD was recovered with a gold layer to allow a laser CD player to read information written on the CD and to read the interference due to silver precipitate (Fig. 2 and 3).” So while the specification does set forth means for reading information on a disc and for detecting signal (silver precipitate), such is of but a single embodiment and then requires additional steps. The specification does not set forth in sufficient detail the claimed method of detecting precipitates or the fixation of but one molecule (claims 30

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and 40-41) to the capture molecules. Further, the specification does not set forth in sufficient detail any assay format where the reagents are allowed to bind to one another while the disc is spinning, wherein said spinning takes place at virtually any speed and wherein the reagents are on any exposed surface of the disc. While applicant has asserted that the claimed invention can be practiced in such a manner, a review of the disclosure fails to find an adequate written description of such a methodology so as to reasonably suggest that applicant was in possession of said method at the time of filing.

14. The specification is similarly silent as to how one is to read any registration (binary) data when the reading of such information is to occur subsequent to any binding and when the surface of the CD has been coated with an agent that would limit non-specific binding and the coating of the entire surface of the CD would effectively block the reading of binary data recorded in other regions of the CD's track.

15. In accordance with claim 34 one is to detect and/or quantify the target molecule by way of detecting variations of a magnetic field. Example 5, found at page 30, last paragraph, bridging to page 31, of the specification, only each what could be achieved. The specification fails to teach with sufficient detail just how capture molecules are to be positioned on non-grooved surfaces and are to be subsequently read by any of a plethora of means, then there is no recited means for identifying just where the various capture molecules are located, nor means to identify/correlate the signal from any given site to any one or combination of capture molecules. Such forward-looking language does not reasonably suggest that applicant was in possession of such a method of conducting the claimed assay at the time of filing.

Response to argument

16. At page 8 of the response received 09 December 2004, hereinafter the response, applicant's representative directs attention to Appendix 1 as providing evidence that CDs and DVDs may be manufactured in a variety of forms.

17. The above argument, and accompanying showing, have been fully considered and have not been found persuasive or inspection of the material provided in Appendix 1 was not published on or prior to the date the instant application was filed. In particular, the material provided via Appendix 1 all bear a date of "6/18/2004," which has been construed as the date it was printed. A review of the material fails to locate any showing of the material contained therein was publicly available prior to the noted date. In comparison, the instant application was filed on 08 November 2000, and has a priority date of 30 December 1997. With there being no evidence of record that establishes that as of, or prior to 30 December 1997, means for making and using CDs and/or DVDs of virtually any shape were commercially available, and the specification not providing an adequate written description on its own of such embodiments, the rejection is maintained.

18. At page 9 of the response received 09 December 2005, applicant's representative directs attention to Figure 7 as demonstrating that two readers are reading a CD.

19. The above argument has been fully considered and has not been found persuasive towards the withdrawal of the rejection for while the figure does show the use of two readers, the tracks of the CD have been construed as being a microchannel, which the claimed method is now proscribed from using. Further, the aspect of reading the CD with two readers, one laser and one magnetic, as presented in Fig. 7, would not result in the detection and/or quantification of any

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signal associated with the binding of a target molecule to a capture molecule as the CD presented in Fig. 7 does not reflect that there are any binding members present. Rather, the figure shows loosely associated ferro-magnetic compound on the surface of a CD. At no place in the figure is there any representation of any specific binding pair interacting, and that the signal obtained, if any, can be correlated to any binding event. Contrary to applicant's representative's assertions, the drawing of Fig. 7 suggests that one would obtain false/uninformative signals.

20. Applicant's representative, at page 9, last line, bridging to page 10 of the response, asserts what one of skill in the art would appreciate.

21. This argument has been fully considered and has not been found persuasive. Attention is directed to MPEP 2145.

Attorney argument is not evidence unless it is an admission, in which case, an examiner may use the admission in making a rejection. See MPEP § 2129 and § 2144.03 for a discussion of admissions as prior art.

The arguments of counsel cannot take the place of evidence in the record. In *re* Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In *re* Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a *prima facie* case of obviousness."). See MPEP § 716.01(c) for examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration.

22. At page 10 of the response argument is advanced that it is "not require[d] that the CD be coated with an agent that would protect the surface of the solid support," but that this is but one embodiment. Argument is advanced that the specification adequately describes this and alternative embodiments.

23. The above argument has been fully considered and has not been found persuasive for while not coating the solid support is asserted to be but one embodiment, the specification fails

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to provide an adequate written description of how the assay is to be conducted so as to minimize non-specific binding, which leads to background/false positive signals. Further, the specification fails to provide an adequate written description of how the registered data is to be read when not protected. Additionally, the specification does not provide an adequate written description of how the assay is conducted when the two or more reading devices all read the same signal, variations in magnetic field.

24. At page 10, bridging to page 11 of the response, argument is advanced in that claim 47 has been amended so “to recite that registered data are used in indication of the characteristics of capture molecules upon specific areas of said CD or DVD or interpretation of the signal is the result of binding between a target and a capture molecule. How such signal is interpreted is well within the scope of a skilled artisan.”

25. The above argument has been fully considered and has not been found persuasive towards the withdrawal of the rejection. It is noted with particularity that the claim was rejected under 35 USC 112, first paragraph, as it relates to the written description requirement, and not under the enablement requirement. Accordingly, the ease or difficulty associated with practicing the claimed invention is not dispositive of the need for a full, clear, and concise written description of the invention such that the disclosure reasonably suggests that applicant had possession of the claimed invention at the time of filing.

26. While said claim 47 has been amended, the specification still does not provide the requisite full, clear, and concise description of the claimed invention, with the invention being what ever is now being claimed. Rather than directing attention to where the specification provides this required written description, argument is advanced that such “is well within the

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scope of a skilled artisan.” Such argument is conclusory as it is void of any factual underpinning.

27. It appears that applicant is attempting to satisfy the written description requirement of 35 USC 112, first paragraph, through obviousness. Obviousness, however, cannot be relied upon for satisfaction of the written description requirement. In support of this position, attention is directed to the decision in *University of California v. Eli Lilly and Co.* (Fed. Cir. 1997) 43 USPQ2d at 1405, citing *Lockwood v. American Airlines Inc.* (Fed. Cir. 1997) 41 USPQ2d at 1966:

Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention.

28. For the above reasons, and in the absence of convincing evidence to the contrary, claims 30-31, 34, 40-4, 44-45, 47, and 64 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

29. The following is a quotation of the second paragraph of 35 U.S.C. 112:

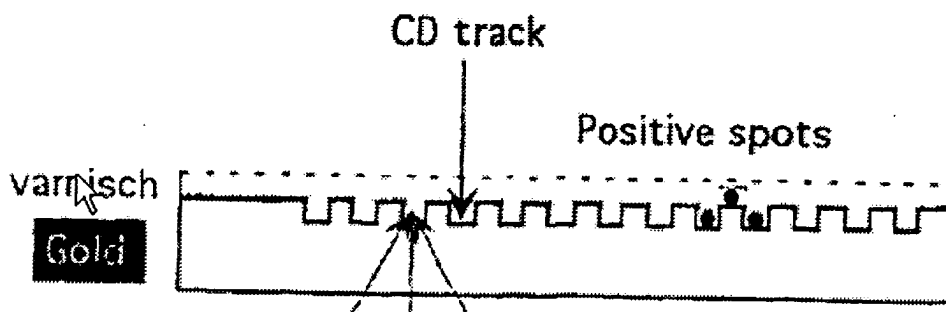
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

30. Claims 30-31, 34, 40-41, 44-45, 47 and 64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

31. Claim 30 is confusing in that the solid surface is to be that of a compact disc (CD) or a digital video disc (DVD), which is recognized as having grooves on its surface. Said claim

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requires the solid support (i.e., the CD or DVD) to not comprise “microchannels.” Fig. 3, *infra*, depicts the tracks, which appear to be microchannels.



It is unclear how a CD or DVD, which is recognized as having radial tracks that in essence form microchannels, yet said CD/DVD cannot have any microchannels. (Page 13, third paragraph, of the specification teaches that a CD may up to 20000 different radial tracks.) Claims 31, 34, 40-41, 44-45, 47, and 64, which depend from said claim 30, fail to overcome this issue and are similarly rejected.

32. Claim 41 speaks of “the detection and/or quantification of the signal.” Claim 30, from which claim 41 depends, teaches of detection and quantification of a target molecule. Said claim 30 also teaches of “detecting said signal,” however, the claim does not provide antecedent support for detection and/or quantification of the signal.

33. Claim 47 provides for the use of registered data, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

34. Claim 47 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e.,

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results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd. App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Conclusion

35. Rejections and/or objections that appeared in the prior Office action and not repeated hereinabove have been withdrawn.

36. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

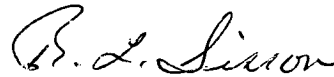
37. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

38. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

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39. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

40. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
08 February 2005